

Name and Registration No.

***Consent Form for Participation in a Research Study***

***n.b. This is one of the current consent forms that is under study through in-depth interviews of participants.***

**TITLE:** "Genetic Determinants of Peripheral Arterial Disease"

**IRB #:** 06-002911 00

**RESEARCHER:** Dr. I. Kullo and colleagues

**PROTOCOL LAST APPROVED BY INSTITUTIONAL REVIEW BOARD:** March 6, 2007

**THIS FORM APPROVED:** March 6, 2007

**This is an important form. Please read it carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study.**

**Why is this research study being done?**

This study is being done to identify new genetic and biochemical markers of peripheral arterial disease.

**How many people will take part in this research study?**

The plan is to have 1600 patients with peripheral arterial disease take part in this study at Mayo Clinic Rochester.

**What will happen in this research study?**

Your participation in the present study will include:

You will be requested to complete a questionnaire at the start of the study. The investigators will ask you to provide information about your cardiovascular history and risk factors for hardening of the arteries.

The investigators will collect a sample of blood (approximately four tablespoons) from a vein in your arm using a needle. If you are scheduled to have blood tests as part of your evaluation at Mayo, then at that time the extra blood for this study would be collected.

The investigators plan to use your blood sample to study your inherited genetic material and other circulating markers that may be involved in the development of vascular disease.

The investigators may review your medical records to examine and verify your medical and surgical history, past physical exams, laboratory tests and treatments. Your blood sample will be coded with a number rather than your name for identification purposes at the Mayo Clinic Rochester. This code will allow your sample to be used without anyone knowing that it is your sample just by looking at the label.

Because the genetic tests or other biochemical tests in this study are not used for regular medical care, you will not be told the results of the test(s). The test results will not be put in your medical record either.

**Additional information you should know:**

The researcher *and/or* Mayo Clinic may earn money from results of this study.

**How long will I be in this research study?**

Your active participation in this study will be the time it takes to complete the questionnaire and have your blood drawn. Your blood sample may be stored indefinitely.

**Are there reasons I might leave this research study early?**

Taking part in this research study is your decision. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers or Mayo may stop you from taking part in this study at any time if it is in your best interest, if you do not follow the study rules, or if the study is stopped.

**Will any biological sample(s) be stored and used for research in the future?**

If you agree to give your sample, it will be the property of Mayo and may be used for research by Dr. Kullo and other staff at Mayo Clinic. Your sample of blood will be stored at Mayo Clinic and given a code (rather than your name) while it is stored and when it is used in research. This code would allow your sample to be used without anyone knowing

that it is your sample just by looking at the label. In addition, researchers at Mayo who are not involved with this study may ask to use your sample for further research.

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. Other researchers may also pay us to use the sample s in their research. If that would happen, you will not be offered a share in any profits. You would not have any ownership or rights to the information or products that are made using the sample.

Some future studies may be for testing the genes you inherited from your parents (also known as genetic testing). If a researcher finds that future test results may be useful for your health care, you will be contacted and given the choice to learn the test results. At that time you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. No test results from these future studies will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information. Signing this consent form shows your permission for the storage and use of your blood sample in future research.

If you want your sample destroyed at any time, write to the Administrator of the Mayo Clinic Office for Human Research Protection, 201 Building 4-60, 200 First Street Southwest, Rochester, Minnesota 55905. Mayo has the right to end storage of the sample without telling you. If you move please send your new address to Mayo Clinic Rochester, Section of Registration, 200 First Street Southwest, Rochester, Minnesota 55905.

## **How do researchers from other institutions get the sample?**

Researchers from universities, hospitals, and other health organizations conduct research using tissue. They may contact Mayo and request samples for their studies and Mayo may send the tissue sample(s) and some information about you to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the sample. If these researchers use the sample for future research and decide that a test result may be useful for your health care, they may contact the Mayo Clinic and Mayo would then contact you to offer you the choice to learn the test results. Signing this consent form shows your permission to give your blood samples to outside researchers.

## **What are the risks of this research study?**

There are no physical risks involved in this study. This study is being done to gather information. There may be slight discomfort involved in obtaining a blood sample from a vein in your arm. Occasionally a bruise can occur at the site where blood was taken. No other physical risks are anticipated from study participation in this proposed investigation.

Providing names and addresses of your relatives to the investigators may be perceived by some family members as an invasion of privacy, and this could impact family relationships.

In the present study, your blood will be tested for genes that you inherited from your parents (also known as genetic testing). No test results from this study will be put into your medical record unless you choose to learn the results of the testing. If the researchers find that the genetic test results may be useful for your health care, you will be contacted and given the choice to learn the test results. At that time you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information.

A pregnancy test will not be necessary as part of this study because there is no risk to an unborn child in this investigation.

### **Are there benefits to taking part in this research study?**

This study may not make your health better. However, we hope that the information learned from this study will lead to better understanding of early onset vascular disease and hopefully to new approaches for its prevention, diagnosis and treatment of vascular disease.

### **What other choices do I have if I don't take part in this research study?**

This study is only being done to gather information. You may choose not to take part in this study.

### **Will I need to pay for the tests and procedures?**

You will not need to pay for any procedures and tests which are done just for this research study. These procedures and tests include collection, preparation and genetic analysis of your blood sample. However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular medical care.

### **What happens if I am injured because I took part in this research study?**

If you have side effects from the study treatment, you need to report them to the researcher and your regular physician, and you will be treated as needed. Mayo will give medical services for treatment for any bad side effects from taking part in this study. Such services will be free if not covered by a health plan or insurance. No additional money will be offered.

### **What are my rights if I take part in this research study?**

Taking part in this research study does not take away any other rights or benefits you might have if you did not take part in the study. Taking part in this study does not give you any special privileges. You will not be penalized in any way if you decide not to take part or if you stop after you start the study. Specifically, you do not have to be in this study to receive or continue to receive medical care from Mayo Clinic.

You will be told of important new findings or any changes in the study or procedures that may affect you or your willingness to continue in the study.

### **Who can answer my questions?**

You may talk to Dr. Kullo at any time about any questions or concerns you have on this study. You may contact Dr. Kullo (or an associate) by calling the Mayo operator at telephone (507) 284-2511.

You can get more information about Mayo policies, the conduct of this study, or the rights of research participants from Marcia L. Andresen-Reid, Administrator of the Mayo Clinic Office for Human Research Protection, telephone (507) 266-4000 or toll free (866) 273-4681.

### **Authorization To Use And Disclose Protected Health Information**

Your privacy is important to us, and we want to protect it as much as possible. By signing this form, you authorize Mayo Clinic Rochester and the investigators to use and disclose any information created or collected in the course of your participation in this research protocol. This information might be in different places, including your original medical record, but we will only disclose information that is related to this research protocol for the purposes listed below.

This information will be given out for the proper monitoring of the study, checking the accuracy of study data, analyzing the study data, and other purposes necessary for the proper conduct and reporting of this study. If some of the information is reported in published medical journals or scientific discussions, it will be done in a way that does not directly identify you.

This information may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information relating to behavioral or mental health services or treatment and treatment for substance abuse

This information may be given to other researchers in this study (including those at other institutions), representatives of the company sponsoring the study (including representatives in the U.S. or other countries), or private, state or federal government parties or regulatory authorities (U.S. and other countries) responsible for overseeing this research. These may include the Food and Drug Administration, the Office for Human Research Protections, or other offices within the Department of Health and Human Services, and the Mayo Clinic Office for Human Research Protections or other Mayo groups involved in protecting research subjects.

If this information is given out to anyone outside of Mayo, the information may no longer be protected by federal privacy regulations and may be given out by the person or entity that receives the information. However, Mayo will take steps to help other parties understand the need to keep this information confidential.

This authorization lasts forever.

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You may stop this authorization at any time by writing to the following address:

Mayo Clinic  
Office for Human Research Protection  
ATTN: Notice of Revocation of Authorization  
200 1st Street SW  
Rochester, MN 55905

If you stop authorization, Mayo may continue to use your information already collected as part of this study, but will not collect any new information.

A copy of this form will be placed in your medical record.

**I have had an opportunity to have my questions answered. I have been given a copy of this form. I agree to take part in this research study.**

\_\_\_\_\_  
(Date / Time)                      \_\_\_\_\_  
(Printed Name of Participant)                      \_\_\_\_\_  
(Clinic Number)

\_\_\_\_\_  
(Signature of Participant)

\_\_\_\_\_  
(Date / Time)                      \_\_\_\_\_  
(Printed Name of Individual Obtaining Consent)

\_\_\_\_\_  
(Signature of Individual Obtaining Consent)